

Notice of Allowability

Application No.

10/826,175

Examiner

Michael P. Barker

Applicant(s)

GUY ET AL.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/13/06.
2. ☒ The allowed claim(s) is/are 1;4-16;27;32;35-36.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>1</u> . |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>4/13/06;6/13/06</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION

The methods of **Claims 17-26** are patentably distinct from the methods of **Claims 29-31** are patentably distinct from the methods of **Claims 32-36** and require further restriction. Applicant has canceled **Claims 2-3, 17-26, 29-31, and 33-34**. Applicant has amended **Claims 1, 5, 7-15, 27, 32, and 35-36**. Therefore, **Claims 1, 4-16, 27, 32, and 35-36** are pending in this application.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on April 13, 2006 and June 13, 2006 were correctly filed. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements were considered by the examiner. Please refer to Applicant's copies of PTO-1449 submitted herewith.

Response to Remarks/Arguments Document

In response to the Remarks/Arguments document filed April 13, 2006, the previous restriction requirement put forth is hereby withdrawn as between Groups I and II. Group II is rejoined and subject to further restriction. The rejections put forth in the Non-final Office Action are hereby withdrawn.

Restriction Requirement

As stated in the summary above, the methods of Group I, **Claims 17-26**, Group II, **Claims 29-31**, and Group III, **Claims 32-36**, are each patentably distinct from one another and therefore require further restriction. Each of Groups I-III is drawn to different, patentably

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distinct methods of using the compounds of the general formula depicted in **Claim 1**, such that a reference anticipating the method of Group I would not necessarily anticipate nor render obvious the method of Group II or Group III.

A telephonic restriction was made June 15, 2006, and Group III was elected without traverse. Therefore, the inventions of Groups I and II are withdrawn without prejudice to Applicant's right to file divisional applications on this subject matter.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it must be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Joel Ackerman on June 15, 2006. The application has been amended as follows:

1. **Claim 1**, p. 3 of 10, delete "Z is $-\text{CH}_2$, $-\text{CH}(\text{CH}_3)-$, $\text{C}(\text{CH}_3)_2-$ or $-\text{CO}-$;" and insert "*n* is zero" therefor.
2. **Claim 1**, p. 3 of 10, before the words, "hydrates and salts thereof," delete "and".
3. Cancel **Claims 2, 3, 17-26, 28-31, 33, and 34**.
4. **Claim 6**, p. 4 of 10, after the words, "A compound according to claim", delete "5" and insert "3" therefor.
5. **Claim 13**, p. 4 of 10, after the words "A compound according to claim", delete "3" and insert "1" therefor.

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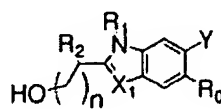
6. **Claim 14**, p. 4 of 10, after the words “A compound according to claim”, delete “3” and insert “1” therefor.
7. **Claim 15**, p. 4 of 10, after the words “A compound according to claim”, delete “3” and insert “1” therefor.
8. **Claim 27**, p. 7 of 10, delete “Z is $-\text{CH}_2$, $-\text{CH}(\text{CH}_3)-$, $\text{C}(\text{CH}_3)_2-$ or $-\text{CO}-$,” and insert “ n is zero” therefor.
9. **Claim 32**, p. 8 of 10, after the words, “A method for treating a cancer”, insert the words, “selected from the group consisting of human lung cancer, human mesothelioma and human melanoma”.
10. **Claim 35**, p. 8 of 10, after the words, “A method for treating a cancer”, insert the words, “selected from the group consisting of human lung cancer, human mesothelioma and human melanoma in cancerous cells or”. After the words, “in a patient comprising”, insert the words, “contacting the cancerous cells with, or”.
11. **Claim 35**, p. 8 of 10, after the words, “effective amount of a compound according to claim”, delete “11” and insert “9” therefor.
12. **Claim 36**, p. 8 of 10, after the words, “A method for treating a cancer”, insert the words, “selected from the group consisting of human lung cancer, human mesothelioma and human melanoma in cancerous cells or”. After the words, “in a patient comprising”, insert the words, “contacting the cancerous cells with, or”.
13. **Claim 35**, p. 8 of 10, after the words, “effective amount of a compound according to claim”, delete “15” and insert “14” therefor.

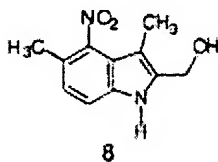
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The aforementioned amendments, namely amendment 10 and amendment 12, correct the Claims to account for the new claim numbering resulting from the canceled claims.

Reasons for Allowance

Applicant's invention is drawn to compounds and compositions of the general formula

depicted in **Claim 1**, , as well as a method of using those compounds and compositions. The closest prior art is Xing, et al. "Design of Cancer-Specific Antitumor Agents Based on Aziridinylcyclopent[b]indoloquinones", J. Med. Chem. 43(3), 457-66 (2000). Xing, et



al. discloses the following compound:

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[p. 458, "Scheme 2" compound 8]. The

disclosed compound is most notably distinguished from the instantly claimed invention, as it is not N-substituted, as is the claimed invention. The claimed invention requires a substitution at the N-position of the indole, a substitution other than a hydrogen atom. Xing, et al. does not meet each and every limitation of nor render obvious the claimed invention. Therefore, the compounds and compositions, being free of the prior art, are allowed. Further, Applicant discloses support in the Specification for the method claims, such that one skilled in the art is capable of using the claimed compounds as claimed by Applicant.

Conclusion

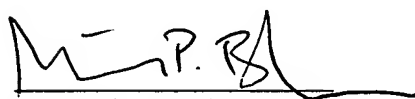
The claimed compounds and compositions, as well as the method for using those compounds and compositions are ALLOWED.

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Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P. Barker whose telephone number is (571) 272-4341. The examiner can normally be reached on Monday-Friday 8:00 AM- 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699. The unofficial fax phone for this group are (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is viable through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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